

## **REMARKS**

Claims 11-36 are pending in the application. Claim 11 has been amended. Claim 27 has been cancelled.

### **I. Update to Specification.**

At page 2 of the Office Action, the Examiner has requested that the applicants update the specification regarding related cases as this application is a CIP of serial number 09/563,707.

The applicants respectfully submit that the specification, at paragraph [0002] reflects this priority claim. Accordingly, the Examiner's objection is believed to be inapplicable and its reconsideration and withdrawal are requested.

### **II. Rejection Under 35 U.S.C. § 103(a).**

The Examiner has rejected claims 11-36 under 35 U.S.C. § 103(a) as being unpatentable over the combination of U.S. Patent No. 5,795,730 of Tautvydas ("Tautvydas") taken in view of U.S. Patent No. 3,770,351 of Wyatt ("Wyatt"). In support of this rejection, the Examiner argues that Tautvydas teaches "a more rapid determination" method that provides an indication of sterilization effectiveness. Tautvydas teaches that as spores germinate, they absorb water and lose the capability of scattering light in spore containing suspensions. The method of Tautvydas according to the Examiner is used in combination with a variety of sterilization methods such as steam, ethylene oxide, radiation, heat, and chemicals. Tautvydas teaches that linear reaction velocities may be determined using known light scattering techniques and spore germination rates may be determined nephelometers based on light scattering. In col. 4, lines 25-33, the Examiner points out that Tautvydas teaches that the rate of spore germination allows a prediction of the number of viable surviving spores, and the method of Tautvydas uses *Bacillus Stearothermophilus* and *subtilis* spores.

The Examiner concedes that Tautvydas does not include limitations directed to multi-angle light scattering. However, the Examiner attempts to remedy this deficiency by application of the disclosure of Wyatt in which detectors that are positioned at a number of different angles in relation to the point of intersection between the light and particle stream are used to analyze a sample containing spores.

Thus, the Examiner reasons:

It would have been obvious to one of ordinary skill in this art at the time the invention was made to employ known light scattering techniques in the method of Tautvydas such as those taught by Wyatt who teaches multi angle light scattering because Tautvydas teaches germinating spores lose [sic] the ability to scatter light because they change shape by absorbing water. One would have a high expectation of success in employing known light scattering measures for their known function with the expected result. The presently claimed photometers are known and nephelometers employ an angle between incident and determined light.

The applicants respectfully traverse the rejection.

The applicants respectfully point out that the Examiner appears to have misunderstood the claimed invention. The invention is not a method of examining the viability of sterilant-treated bacterial spores by determining the rate of germination. Rather, the invention is directed to a method of assessing the viability of a spore after a sterilization treatment, such method including a step of evaluating the difference between:

- (a) the multi-angle light scattering of a treated spore, and
- (b) a multi-angle light scattering of a like spore not exposed to a sterilization treatment, in order to evaluate a change in spore morphology and/or a change in the number of spores to determine whether the treated spore is viable, and therefore to deduce the efficacy of the sterilization treatment.

For example, as described in the specification at page 25, line 4, to page 26, line 5, the method of the invention may include the comparison of light scattering profiles of a treated spore sample and a standard light scattering profile of an untreated spore. Such profiles are obtained by multi-angle light scattering analysis. The method of the invention recites an evaluation of viability through the above-described comparison. It does not recite, require, or even address the determination of the presence or absence of germination, the rate of germination, or any other aspect of spore germination and/or vegetative proliferation.

In contrast, Tautvydas discloses a method to assess and determine the effectiveness of a sterilization process that requires that the viability of the sterilant-treated spore is determined by analysis of spore germination kinetics, specifically by a calculation of rate of germination of the treated spores, which allows for a prediction of the number of surviving spores. Tautvydas teaches that the rate of germination correlates directly with the "kill curves" of viable microbes

associated with a bioburden of a sample to which a sterilization process has been applied. *See*, col. 4, lines 1-8. Thus, once such rate is obtained, one may make an extrapolation of about the viability/non-viability of the treated spores. *See, e.g.*, Figure 3.

It is taught in Tautvydas that the rate of germination can be calculated by using the change in absorbance (optical density) or light scattering over a time of application of sterilization procedure. Using absorbance of light scattering data, Tautvydas teaches that a maximum germination rate (LRV), can be calculated and plotted against a kill curve to provide a description of the relationship between the number of minutes to which the spores are subjected to a sterilization process, and the number of spores that remain viable. No specific disclosure is provided regarding the use of light scattering techniques for the gathering of data.

Wyatt teaches a method and apparatus for identifying submicroscopic particles by directing the particles through a highly collimated beam of light and simultaneously measuring light intensity at a plurality of different angles relative to the point where the particles move through the light beam. Wyatt discloses that the method can be used to determine electromagnetic characteristics, shape, and size of microparticles.

To establish a *prima facie* case of obviousness, the Examiner must demonstrate: (i) that the suggested combination teaches or suggests each element of the claimed invention; (ii) that there was a motivation in the art to make the combination and (iii) that a person of ordinary skill would have reasonably expected the combination to be successful.

The Examiner has failed to establish a *prima facie* case of obviousness based upon the Tautvydas-Wyatt combination. First, the combination fails to teach or suggest the invention as claimed. The invention is, as is discussed above, a method of assessing the viability of a spore after a sterilization treatment, including the evaluation of the difference between (a) the multi-angle light scattering of the treated spore and (b) a multi-angle light scattering of a spore not exposed to a sterilization treatment, in order to evaluate a change in spore morphology and/or a change in number of spores and (b) as described above, in order to evaluate a change in spore morphology and/or a change in number of spores to determine whether the treated spore is viable.

Rather Tautvydas teaches that the viability assessment can be determined by calculation of the rate of germination of any viable spore. As a means of obtaining the raw data from which the rate of germination can be calculated, Tautvydas specifically teaches use of

spectrophotometric techniques to ascertain germination over time, and generally states that nephelometric techniques may be used. That the data used in the viability analysis in the claimed invention are gathered by a light scattering analytical technique and the data used in the method of Tautvydas may perhaps be gathered by a light scattering technique is irrelevant to the patentability analysis as the methods of evaluation (namely, a comparison of (a) and (b) as described above versus determination of rate of germination) are not the same.

Combining Wyatt with Tautvydas does not remedy any of the deficiencies of Tautvydas; the missing elements of the method remain. Wyatt teaches only an optical analyzer for microparticle, which permits, by analysis of scattered light from several angles, a rapid, quantitative analysis of the physical properties of a microscopic particulate matter such as its electromagnetic characteristics, its shape, and its size. Wyatt does not teach or suggest that any data or other analysis obtained by use of the Wyatt method can be utilized in any method for assessing the viability of a spore by any method, let alone the method of the invention.

Thus, the Tautvydas-Wyatt combination put forth by the Examiner fails to teach or suggest each element of the invention as claimed. Accordingly, the present invention is not rendered obvious in view of such combination.

Further, even if Tautvydas-Wyatt did teach or suggest each element of the invention, which it does not, the Examiner has still failed to make a *prima facie* case of obviousness, as there is no motivation in the art which would have caused a person of ordinary skill to make the combination proposed by the Examiner. Tautvydas teaches that a viability determination is made by an analysis of the germination kinetics determined from a sample of spores exposed to a specific sterilization process. Germination, as was well known to a person of skill in the art, involves a formation of bright bodies which results in a morphological change of the spore. Tautvydas teaches that the rate of germination can be calculated using data obtained by absorbance spectrophotometry, and/or light scattering techniques. However, no specific examples and no specific description are provided in Tautvydas that utilize light scattering techniques for the viability assessment, *i.e.*, to calculate the rate of germination, nor is an equation provided for the calculation of LRV using such data. In the absence of these clues, a person of ordinary skill in the art would not have been motivated to combine Tautvydas with Wyatt (a light scattering method) in order to arrive at the present invention. Further, in the absence of any specific, concrete examples using data obtained by light scattering in Tautvydas,



a person of skill would have had no reasonable expectation that the combination would have been successful.

Wyatt teaches a method of multi-angle light scattering. It does not teach or suggest that its method can be used to make a determination of rate of germination of a spore population, in order to carry out a viability assessment. Thus, a person of ordinary skill would have had no reason to make the combination of Tautvydas and Wyatt suggested by the Examiner.

For at least these reasons, it is respectfully submitted that the Examiner has failed to make a *prima facie* case of obviousness based upon the Tautvydas-Wyatt combination. Accordingly, it is respectfully requested that the Examiner reconsider the § 103 rejection.

### **III. Rejections Under 35 U.S.C. § 112, second paragraph.**

The Examiner has rejected claims 11-13 under 35 U.S.C. § 112, second paragraph, contending that they are indefinite. Namely, the Examiner contends that in claim 11, line 1, the viability lacks antecedent basis. The applicants traverse this rejection. As is known to a person of skill in the art, a living organism, such as a spore, has only one state of being viable, it is either alive or it is dead. Thus it is submitted that changing "the" to "a" would be make little sense.

The Examiner objects to claim 11 for use of "the treated" in step b. Claim 11 has been amended to make clear that "the treated spore" is the spore of step a, as is consistent with the ordinary meaning of the sentence that is claim 11.

The Examiner has rejected claim 25 contending that "the efficacy" lacks an antecedent basis. The applicants disagree with the Examiner. As is known to a person of skill in the art, the state of being efficacious is either present or not present; thus, changing "the efficacy" to "an efficacy" would not make sense.

The Examiner has rejected claim 27 for use of trademarks. Claim 27 has been cancelled.

In view of the foregoing, it submitted that the Examiner's rejections under 35 U.S.C. § 112, second paragraph, are either inapplicable or have been overcome. Reconsideration and withdrawal of the rejections is respectfully requested.

### CONCLUSION

In view of the foregoing, it is submitted that claims 11-26 and 28-36, are patentably distinguished over the cited prior art. Reconsideration of the rejections and allowance of the claims at the earliest opportunity are respectfully requested.

Respectfully submitted,

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22 November 2004  
(Date)

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Enclosures [Petition for Extension of Time]